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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,295	03/22/2004	Paulo LaColla	11874-076-999	1837
20583	7590	09/03/2009	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			CRUZ, KATHRIEN ANN	
			ART UNIT	PAPER NUMBER
			1617	
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			09/03/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/806,295	Applicant(s) LACOLLA ET AL.	
	Examiner KATHRIEN CRUZ	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8,9,12,13,19-46 and 49-65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 57-65 is/are allowed.
- 6) ☐ Claim(s) 8,9,12,13,19-46 and 49-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>03/20/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 8, 9, 12, 13, 19-46 and 49-65 are pending.

Claims 8, 9, 12, 13, 25-26 are withdrawn.

Claims 19-24, 27-46 and 49-65 are examined herewith.

Applicants response filed March 20, 2009 has been received and entered in the application.

Priority

This application is a division of 10/122252 (dated 04/11/2002) which claims benefits of provisional application 60/283,393 (dated 04/11/2001).

Action Summary

Claims 19-24, 27-46 and 49-56 are rejected under 35 U.S.C. 102(b) as being anticipated by Williams (EP 0530907) of record is withdrawn. However, upon further consideration the new rejection is made below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

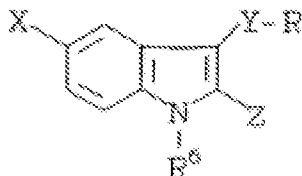
The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 19-24, 27-46 and 49-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams (EP 0530907).

Instantly claimed compounds and the method of treating HIV are disclosed at page 3 and abstract of Williams. At page 3, see the Formula A. The compounds for the treatment of HIV are depicted below:



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X is **-H, -Cl, -F**, -Br, -NO₂, -CN, or -OR₂;Y is "**S(O)ⁿ**", "CR₂R~" or -O-, wherein n is zero, 1 or 2;

R is

1) hydrogen,

2) -C~-salkyl, unsubstituted or substituted with one or more of:

a) -O¹ -salkyl,

b) -C~ -s alkoxy,

c) -OH, or

d) **aryl**, unsubstituted or substituted with one or more of:i) -C₁₋₅; -s alkyl,ii) -C₁₋₅; -s alkoxy,

iii) -OH, or

iv) halogen,

Z is

1)



||

W,

wherein W is O, S, -N-CN or -N-OR',

2)



||

O

R² is hydrogen or, C₁₋₃ alkyl and R³ is hydrogen, C₁₋₅ alkyl, aryl, or heterocycle.R⁶ is hydrogen. (page 3-6).

The claimed compounds for the treatment of HIV is fully met when x is **-H, -Cl, -F**; Y is **S(O)ⁿ**; R is **aryl**; and Z is **-C-NR²R³** and W is **O or S**

||

W

Williams teaches in compound 18 (page 15, lines 20-32) a mono-substituted chloro which is used for the treatment of infection by HIV and the treatment of AIDS (abstract).

Williams does not expressly teach di-substituted indol.

It would have been obvious to one of ordinary skill in the art at the time of the invention to have the addition of a methyl group. Compounds that differ only by the presence of an extra methyl group are homologues which are of such close structural similarity that the disclosure of a compound renders prima facie obvious its homologue. The homologue is expected to be preparable by the same method and to have the similar properties. This expectation is then deemed the motivation for preparing homologues. Homologues are obvious even in the absence of a specific teaching to methylate, *In re Wood* 199 USPQ 137; *In re Hoke* 195 USPQ 148; *In re Lohr* 137 USPQ 548; *In re Magerlein* 202 USPQ 473; *In re Wiechert* 152 USPQ 249; *Ex parte Henkel* 130 USPQ 474; *In re Fauque* 121 USPQ 425; *In re Druey* 138 USPQ 39.

For these reasons, the claimed subject matter is deemed to fail to be patentably distinguishable over the state of the art as represented by the cited reference. The claims are therefore, properly rejected under 35 U.S.C. 103. In light of the foregoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

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Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Allowable Subject Matter

Applicants are again reminded that claim 57 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 58-65 are allowable and free of art.

Conclusion

Claims 19-24, 27-46 and 49-56 are rejected.

Claim 57 is objected.

Claims 58-65 are allowable.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHRIEN CRUZ whose telephone number is (571)270-5238. The examiner can normally be reached on Mon - Thurs 7:00am - 5:00pm with every Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KATHRIEN CRUZ/
Examiner, Art Unit 1617

/San-ming Hui/
Primary Examiner, Art Unit 1617